

COMMISSION RECOMMENDATION**of 12 October 1999****on the results of the risk evaluation and on the risk reduction strategies for the substances:****2-(2-butoxyethoxy)ethanol;****2-(2-methoxyethoxy)ethanol;****Alkanes, C₁₀₋₁₃, chloro; Benzene, C₁₀₋₁₃-alkyl derivs.***(notified under document number C(1999) 3232)***(Text with EEA relevance)**

(1999/721/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances ⁽¹⁾ and in particular Article 11(2) thereof,

- (1) Whereas Article 10 of Regulation (EEC) No 793/93 establishes the procedure to be followed for the risk evaluation of the substances on the priority lists at the level of the Member States designated as rapporteur;
- (2) Whereas Commission Regulation (EC) No 1488/94 ⁽²⁾ outlines the principles for the assessment of risks to man and the environment of existing substances in accordance with Regulation (EEC) No 793/93,
- (3) Whereas the Member State rapporteur after evaluating the risk of a given priority substance to man and the environment shall suggest where appropriate a strategy for limiting this risk, including control measures and/or surveillance programmes;
- (4) Whereas Article 11 of Regulation (EEC) No 793/93 foresees that the results of the risk evaluation and the recommended strategy for limiting risks in respect of substances on the priority lists should be adopted at Community level in accordance with the procedure laid down in Article 15 and shall be published by the Commission;
- (5) Whereas Article 1 of Regulation (EEC) No 793/93 foresees that this Regulation shall apply without prejudice to Community legislation on the protection of consumers and on safety and protection of health of workers at work, in particular Council Directive 89/391 EEC;
- (6) Whereas a first priority list identifying priority substances requiring attention has been adopted by Commission Regulation (EC) No 1179/94 ⁽³⁾; whereas this priority list provides, among other substances, for the evaluation of the following:

— 2-(2-butoxyethoxy)ethanol,

— 2-(2-methoxyethoxy)ethanol,

⁽¹⁾ OJ L 84, 5.4.1993, p. 1.⁽²⁾ OJ L 161, 29.6.1994, p. 3.⁽³⁾ OJ L 131, 26.5.1994, p. 3.

— Alkanes, C₁₀₋₁₃, chlor,

— Benzene, C₁₀₋₁₃-alkyl derivs.

- (7) Whereas the Member States rapporteur for the four substances have completed all the risk evaluation activities with regard to man and environment⁽¹⁾ and, where appropriate, have suggested strategies for limiting these risks;
- (8) Whereas the results of the risk evaluation of the four substances and the recommended risk reduction strategies for three of the four substances concerned should be adopted at Community level;
- (9) Whereas in accordance with Article 11(3) of Regulation (EEC) No 793/93 the Commission will consider the results of the risk evaluation and the recommended strategy for limiting the risks, when proposing Community measures in the framework of Council Directive 76/769 EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations⁽²⁾ and in the framework of Council Directive 89/391 EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work⁽³⁾, as well as in the framework of other relevant existing Community instruments;
- (10) Whereas the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) has been consulted and has issued an opinion with respect to the risk assessment reports referred to in this recommendation;
- (11) Whereas the measures provided for in this recommendation are in accordance with the opinion of the Committee set up pursuant to Article 15 of Regulation (EEC) No 793/93.

HEREBY FORMULATES THIS RECOMMENDATION:

1. All sectors producing, transporting, storing, formulating into a preparation or other processing, using and disposing or recovering the following substances:

— 2-(2-butoxyethoxy)ethanol
CAS No 112-34-5
Einecs No 203-961-6

— 2-(2-methoxyethoxy)ethanol
CAS No 111-77-3
Einecs No 203-906-6

— Alkanes, C₁₀₋₁₃, chloro
CAS No 85535-84-8
Einecs No 287-476-5

should take into account the results of the risk evaluation as summarised in Section I (human health/environment) of Parts 1, 2, 3 of Annex I to this recommendation. These results were formulated in the light of the opinions delivered by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE)⁽⁴⁾.

2. The risk reduction strategies described in Section II (strategy for limiting the risks), Parts 1, 2, 3 of Annex I to this recommendation should be implemented.

⁽¹⁾ The comprehensive risk assessment reports as forwarded to the Commission by the Member States rapporteur are publicly available. Short summaries are also available. Both can be obtained by contacting the European Chemicals Bureau, Institute for Health and Consumer Protection of the Joint Research Centre in Ispra, Italy.

⁽²⁾ OJ L 262, 27.9.1976, p. 201.

⁽³⁾ OJ L 183, 29.6.1989, p. 1.

⁽⁴⁾ The risk evaluation reports were peer-reviewed by the CSTEE and its opinions were expressed at the sixth CSTEE plenary meeting held in Brussels on 27 November 1998. The CSTEE opinions can be found on the Internet (http://www.europa.eu.int/comm/dg24/health/sc/sct/outcome_en.html).

3. All sectors producing, transporting, storing, formulating into a preparation or other processing, using and disposing or recovering the following substance:

- Benzene, C₁₀₋₁₃-alkyl derivs.
CAS No 67774-74-7
Eines No 267-051-0

should take into account the results of the risk evaluation as summarised in Section I (Human health/environment) of Annex II to this recommendation. These results were formulated in the light of the opinion delivered by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE).

Done at Brussels, 12 October 1999.

For the Commission
Margot WALLSTRÖM
Member of the Commission

ANNEX I

PART ONE

CAS No 112-34-5

Einecs No 203-961-6

CH₃-(CH₂)₃-O-CH₂-CH₂-O-CH₂-CH₂-OHEinecs name: **2-(2-butoxyethoxy)ethanol**

Member State rapporteur: The Netherlands

Classification: Xi; R 36

The risk assessment is based on current practices related to the life cycle of the substance as described in the risk evaluation forwarded to the Commission by the Member State rapporteur.

The risk assessment, based on the available information, has determined that in the European Community the substance is mainly used in preparations of cleaning agents (e.g. floor and metal cleaners) for industry and public domain. It is further used as solvent in paints and coatings in the industrial and public sector. A minor utilisation of the substance consists in the use as chemical intermediate for butyldiglycol acetate.

I. RISK ASSESSMENT**A. Human health**

The conclusion of the evaluation of the risks to man for

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for anticipated local effects as a consequence of dermal and respiratory exposure arising from manual application of products containing the substance,
- concerns for anticipated general systemic effects as a consequence of repeated respiratory exposure arising from manual application of products containing the substance.

The conclusion of the evaluation of the risks to man for

CONSUMERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for anticipated local effects as a consequence of respiratory exposure arising from spraying application of products containing the substance.

The conclusion of the evaluation of the risks to man for

MAN EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the populations mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusion of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEMS, MICRO-ORGANISMS in the SEWAGE TREATMENT PLANT, ATMOSPHERE, TERRESTRIAL ECOSYSTEM and NON-COMPARTMENT SPECIFIC EFFECTS RELEVANT to the FOOD CHAIN

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environment spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

II. STRATEGY FOR LIMITING RISKS

for WORKERS

The legislation for workers' protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed.

Within the framework it is recommended:

- to prescribe as a good practice in the safety data sheets adequate eye protection (goggles) and hand protection (gloves) to all persons handling the pure substance,
- to provide in the safety data sheets information on the risks resulting from the manual application of products containing the substance,
- to provide adequate training and instructions to the workers as well as information and consultation on the risks resulting from the manual application of products containing the substance,
- to develop at Community level occupational exposure limit values for the substance;

for CONSUMERS

It is recommended that paints containing the substance and which are intended for spray applications should not be made available to consumers. Furthermore, paints containing the substance and which are available to consumers, should contain a use instruction on the product to clearly indicate that they should not be sprayed.

In the first place it is recommended to pursue these objectives through a unilateral self-binding commitment made by the producers, the importers of the substance, the trade organisations representing the companies manufacturing the products containing the substance (the formulators). The commitment should be recognised by the public authorities. The producers, the importers of the substance and the formulators should subsequently implement the measures and monitor the compliance to the commitment periodically. The results achieved should be assessed at regular intervals and appropriate additional measures should be considered if necessary.

PART TWO

CAS No 111-77-3

Einecs No 203-906-6

CH₃-O-CH₂-CH₂-O-CH₂-CH₂-OH

Einecs name: **2-(2-methoxyethoxy)ethanol**

Member State rapporteur: the Netherlands

Classification: Repr. Cat. 3; R 63

The risk assessment is based on current practices related to the life cycle of the substance as described in the risk evaluation forwarded to the Commission by the Member State rapporteur.

The risk assessment, based on the available information, has determined that in the European Community the substance is mainly used as an anti-icing agent in jet fuel. Further uses are as a chemical intermediate, basic chemical (processing solvent), in paint strippers and solvent in paints or floor polish.

I. RISK ASSESSMENT

A. Human health

The conclusion of the evaluation of the risks to man for

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for anticipated general systemic effects as a consequence of repeated dermal exposure arising from production of the substance, formulation of products containing the substance and manual application of products containing the substance,
- concerns for anticipated developmental effects as a consequence of dermal exposure arising from formulation of products containing the substance and manual application of products containing the substance.

The conclusion of the evaluation of the risks to man for

CONSUMERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for general systemic and developmental effects as a consequence of exposure arising from consumer use of paints or paint strippers containing the substance.

The conclusion of the evaluation of the risks to man for

MAN EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the populations mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusion of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM, MICRO-ORGANISMS in the SEWAGE TREATMENT PLANT, ATMOSPHERE, TERRESTRIAL ECOSYSTEM and NON-COMPARTMENT SPECIFIC EFFECTS RELEVANT to the FOOD CHAIN

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

II. STRATEGY FOR LIMITING RISKS

for WORKERS

The legislation for workers protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed.

Within this framework it is recommended:

- to provide as a good practice additional information on the risks resulting from the production of the substance, formulation of products containing the substance and manual application of products containing the substance, for instance in the safety data sheets,
- to emphasise risks posed to women in the reproductive age,
- to provide adequate training and instructions to the workers as well as information and consultation on the risks resulting from the manual application of products containing the substance,
- to develop at Community level occupational exposure limit values for the substance;

for CONSUMERS

It is recommended to prevent dermal exposure of consumers to paints and paint strippers containing the substance.

It is recommended to clearly state in use instructions on these products (packaging, containers) the fact that women in the reproductive age are a vulnerable group.

Furthermore, industry should commit itself to substituting the substance in paints and paint strippers for substances posing less risk, without shifting the risks to other human populations or environmental compartments.

In the first place it is recommended to pursue these objectives through a unilateral self-binding commitment made by the producers, the importers of the substance, the trade organisations representing the companies manufacturing the products containing the substance (the formulators). The commitment should be recognised by the public authorities. The producers, the importers of the substance and the formulators should subsequently implement the measures and monitor the compliance to the commitment periodically. The results achieved should be assessed at regular intervals and appropriate additional measures should be considered if necessary.

PART THREE

CAS No 85535-84-8

Einecs No 287-476-5

$C_xH_{(2x-y+2)}Cl_y$ where $x = 10-13$ AND $y = 1-13$

Einecs name: **Alkanes, C_{10-13} , chloro**

Member State rapporteur: United Kingdom

Classification: Carc. Cat. 3; R 40
N; R 50-53

The risk assessment is based on current practices related to the life cycle of the substance as described in the risk evaluation forwarded to the Commission by the Member State rapporteur.

The risk assessment, based on the available information, has determined that in the European Community the substance is mainly used as an additive in metal working fluids. Other uses are as a flame retardant in rubber formulations and as an additive for paints and other coating systems. Minor uses reported are as a fatting and softening agent in the leather industry, an impregnation agent in the textile industry and as an additive for sealing compounds. It was not possible to obtain information on the use of the total volume of the substances produced or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

I. RISK ASSESSMENT

A. Human health

The conclusion of the evaluation of the risks to man for

WORKERS, CONSUMERS and MAN EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the population mentioned above are not expected. The main route of potential worker exposure during production and use is via dermal exposure. Inhalation is also a potential route of exposure during use of metal working fluids and hot-melt adhesives containing the substance. Risk reduction measures already being applied in the framework of the workplace or other relevant Community legislation in force are considered sufficient,
- Consumer exposure, which may occur by contact with leather goods treated with the substance and from non-professional use of metal working fluids, was considered not to be of concern.

B. Environment

The conclusion of the evaluation of the risks to the environment for

AQUATIC (sediment) and TERRESTRIAL ECOSYSTEM

is that there is a need for further information and/or testing. This conclusion is reached because:

- there is a need for better information to adequately characterise the risk to sediment compartment arising from production of the substance and its use in rubber, to the soil and sediment compartments arising from the formulation and use of metal working fluids and leather finishing products, and to the soil and sediment compartments at regional level.

The information requirements are:

- experimental determination of the Koc,
- monitoring data in soil and sediment near sources of release,
- toxicity testing on soil and sediment dwelling organisms if the abovementioned information does not remove the concern for the abovementioned compartments.

The conclusion of the evaluation of the risks to the environment for

MICRO-ORGANISMS in the SEWAGE TREATMENT PLANT and ATMOSPHERE

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the evaluation of the risks to the environment for

AQUATIC (excluding sediment) ECOSYSTEM and NON-COMPARTMENT SPECIFIC EFFECTS RELEVANT TO THE FOOD CHAIN

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for effects on the local aquatic environmental spheres mentioned above as a consequence of exposure arising from formulation and use of metal working fluids containing the substance and leather finishing products containing the substance,
- concerns for non-compartmental specific effects relevant to the food chain arising from the formulation and use of leather finishing products containing the substance and from use of metal working fluids containing the substance.

II. STRATEGY FOR LIMITING RISKS

for the ENVIRONMENT

Marketing and use restrictions should be considered at Community level for the substance to protect the environment from the use and formulation of products, in particular for use in metal working and leather finishing. Further work is necessary to establish those uses for which derogations can be justified.

The measures identified to protect the environment will also reduce human exposure.

ANNEX II

CAS No 67774-74-7

Einecs No 267-051-0

CH₃-(CH₂)_m-CH(C₆H₅)-(CH₂)_n-CH₃ where m+n = 7:10Einecs name: **benzene, C₁₀₋₁₃-alkyl derivs.**

Member State rapporteur: Italy

Classification: not yet classified

The risk assessment is based on current practices related to the life cycle of the substance as described in the risk evaluation forwarded to the Commission by the Member State rapporteur.

The risk assessment, based on the available information, has determined that in the European Community the substance is mainly used as an intermediate in the chemical industry for the production of linear alkyl benzenesulphonates. Minor uses reported are as a solvent or binder for asphalt, paints, inks and varnishes. It was not possible to obtain information on the use of the total volume of the substances produced or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

I. RISK ASSESSMENT**A. Human Health**

The conclusion of the evaluation of the risks to man for

WORKERS, CONSUMERS and MAN EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the populations mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusion of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM, MICRO-ORGANISMS in the SEWAGE TREATMENT PLANT, ATMOSPHERE, TERRESTRIAL ECOSYSTEM and NON-COMPARTMENT SPECIFIC EFFECTS RELEVANT TO THE FOOD CHAIN

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied.

This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

II. STRATEGY FOR LIMITING RISKS

None
